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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,879	10/20/2003	Bart Lambert	2428-0125P	2543

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EXAMINER	
PROUTY, REBECCA E	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,879	LAMBERT ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/379,656

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse of Group I, Claims 1-3 in the reply filed on 4/27/06 is acknowledged. The traversal is on the ground(s) that Groups I and II have not been shown to be distinct as the distinct utility cited for the polynucleotides of the Group I, i.e., as a hybridization probe, might not, without more, be a patentable utility as defined in the Utility Guidelines and while the proteins could theoretically be by the alternative means cited by the Office, practicality dictates that the proteins will be manufactured from the DNA that encodes them as chemical synthesis of proteins, as well as their extraction from natural sources, are unnecessarily time-consuming and expensive manufacturing methods. Finally applicants argue that there would not be any additional burden of search of the co-examination of both groups as search for the polynucleotides of Group I and their expression products, i.e. the polypeptides of Group II, requires the use of a computer-based search of the same set of biosequence databases. Applicants argument that a distinct utility for the polynucleotides of Group I has not been shown is not persuasive because the use of *B. thuringiensis* toxin genes as hybridization probes for the isolation and detection of other *B. thuringiensis* toxin genes is well known in the art. As such the genes of Group I do have a utility distinct from their use to produce the

proteins of Group II. Applicants argument that the proteins would not be produced by the alternative means cited by the Office is not persuasive as distinctness for restriction does not require that the alternative means of production be simple and cheap, but merely that it is possible. Both means cited by the Office are clearly possible. Finally applicants argument that there would be no burden of search for coexamination of both groups is not persuasive as searching of Groups I and II would not be done only by computer based search of biosequence databases and the necessary additional word searches would not encompass the same subject matter. For example a complete search of the proteins of Group II, would require word searching for literature teaching non-recombinant isolation of the proteins by standard protein purification techniques. However, such teaching would not be applicable to examination of the polynucleotides of Group I. As such the search of Groups I and II, while overlapping, is not coextensive, and coexamination, would require a substantial additional burden on the Office

The requirement is still deemed proper and is therefore made FINAL.

Claim 4 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely

traversed the restriction (election) requirement in the reply filed on 4/27/06.

Claims 2 and 3 are objected to because of the following informalities: genus and species names of insect species should be either underlined or italicized. Appropriate correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In the absence of the hand of man, naturally occurring DNAs are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated DNA ..." .

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "a variant of the protein of SEQ ID NO:4" as neither the specification nor the claims define what the scope of the term "variant" is. How

similar to SEQ ID NO:4 must a protein be to be within the scope of the term "variant"? For purposes of further examination, the term "variant" is given no patentable weight.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of nucleic acids encoding a polypeptide having insecticidal activity and comprising nucleotides 198-1561 of SEQ ID NO:2 and/or nucleotides 1-1145 of SEQ ID NO:3. The specification does not contain any disclosure of the structure of all nucleic acid sequences included in the claimed genera. The genus of nucleic acids claimed is a large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally distinct nucleic acids are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus (i.e., that of SEQ ID NO:4) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. A sufficient written description of a genus of DNAs may be

achieved by a recitation of a representative number of DNAs defined by nucleotide sequence or a recitation of structural features common to members of the genus, **which features constitute a substantial portion of the genus**. The recited structural feature(s) of the genus (i.e., comprising nucleotides 198-1561 of SEQ ID NO:2 and/or nucleotides 1-1145 of SEQ ID NO:3) does not constitute a substantial portion of the genus as the indicated portions of SEQ ID NOS: 2 and 3 either alone or together are not sufficient to encode a protein having insecticidal activity (note the recited sequences do not encode residues 2035-2994 of SEQ ID NO:4 necessary for encoding residues 456-776 of SEQ ID NO:5 which includes residues necessary for insecticidal activity), the remainder of the structure of any nucleic acid encoding a polypeptide having insecticidal activity is completely undefined and the specification does not define the remaining structural features necessary for members of the genus to be selected. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C.

112, first paragraph, published in the Official Gazette and also available at www.uspto.gov

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding amino acids 44-658 of SEQ ID NO: 5 does not reasonably provide enablement for any nucleic acids encoding a polypeptide having insecticidal activity and comprising nucleotides 198-1561 of SEQ ID NO:2 and/or nucleotides 1-1145 of SEQ ID NO:3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-3 recite nucleic acids encoding a polypeptide having insecticidal activity and comprising nucleotides 198-1561 of SEQ ID NO:2 and/or nucleotides 1-1145 of SEQ ID NO:3. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of toxin genes broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any,

are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. In the case of the toxins of *Bacillus thuringiensis*, while many have been sequenced it is well known that even very minor changes in sequence may affect the insecticidal activity of the protein. Furthermore, little, if any, predictability is exhibited in the effects of these changes and the structural features recited in the instant claims are not sufficient to encode a protein having insecticidal activity as the recited sequences do not encode residues 2035-2994 of SEQ ID NO:4 necessary for encoding residues 456-776 of SEQ ID NO:5 which includes residues necessary for insecticidal activity. However, the specification presents the encoding nucleic acid sequence and amino acid sequence of only a single Bt toxin.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect

any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass an enormous number of variants of the polynucleotide of SEQ ID NO:4 because the specification does **not** establish: (A) regions of the protein structure which may be modified without affecting insecticidal activity; (B) a rational and predictable scheme for modifying the toxin residues with an expectation of obtaining the desired insecticidal activity; and (C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any nucleic acids encoding a polypeptide having insecticidal activity and comprising nucleotides 198-1561 of SEQ ID NO:2 and/or nucleotides 1-1145 of SEQ ID NO:3. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of mutant toxins genes having the desired insecticidal

characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 10 of U.S. Patent No. 6,727,409. An obviousness-type double patenting rejection is appropriate where the

conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-3 herein and claims 6 and 10 of U.S. Patent No. 6,727,409 are all directed to genera of polynucleotides encoding variants of the insecticidal toxin of SEQ ID NO:5. The claims differ in the scope of variants encompassed and structural characteristics that must be present in the recited polynucleotides. The portion of the specification in 6,727,409 that supports the genera of polynucleotides of Claims 6 and 10 of the patent includes embodiments that would anticipate claims 1-3 herein, e.g., SEQ ID NO:4. Claims 1-3 cannot be considered patentably distinct over claims 6-10 of 6,727,409 when there is a specifically recited embodiment that would anticipate claims 1-3 herein. Alternatively, claims 1-3 cannot be considered patentably distinct over claims 6 and 10 of 6,727,409 when there is a specifically disclosed embodiment in 6,727,409 that supports

claims 6 and 10 of that patent and falls within the scope of claims 1-3 herein because it would have been obvious to one having ordinary skill in the art to modify the genera of claims 6 and 10 by selecting a specifically disclosed embodiment that supports that claim, i.e., SEQ ID NO:4. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 6 and 10 of the patent.

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,028,246. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-3 herein recite polynucleotides encoding variants of the insecticidal toxin of SEQ ID NO:5. Claims 1 and 2 of U.S. Patent No. 6,028,246 recite

transformed plant cells comprising polynucleotides encoding the insecticidal toxin of SEQ ID NO:5 or the fragment thereof consisting of amino acids 44-658. While the transformed plant cells of the patent and polynucleotides of the instant application are distinct products, a skilled artisan would have been aware that in order to make the transformed plant cells of the patent the polynucleotide comprised within said cells would be required. As such the transformed plant cells of the patent would clearly suggest the polynucleotide with which they are transformed. Therefore, the polynucleotide encoding the insecticidal toxin of SEQ ID NO:5 or the fragment thereof consisting of amino acids 44-658 would have been obvious to a skilled artisan from the transformed plant cells of claims 1 and 2 of U.S. Patent No. 6,028,246. The polynucleotide encoding the insecticidal toxin of SEQ ID NO:5 would anticipate claims 1-3 herein while the polynucleotide encoding the insecticidal toxin of amino acids 44-658 of SEQ ID NO:5 would anticipate claim 2 herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura

Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rebecca Prouty
Primary Examiner
Art Unit 1652